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HELLIGE

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Section 2 - Summary & Certification

Date 03-09-1995

2.1 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter

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Device

Trade name: CardioSoft / CardioSys
Classification name: Electrocardiograph;
Detector and Alarm, Arrhythmia

Predicate Device

HELLIGE CARDIOGNOST EK 512

Device Description

CardioSoft / CardioSys is an ECG data acquisition and recording system designed and manufactured by HELLIGE GmbH.

CardioSoft / CardioSys allows to
- record resting ECGs,
- run stress test examinations,
- measure and interprete the ECGs.

Intended Use

CardioSoft / CardioSys are intended to be used in resting ECG, emergency- and stress-test departments to record, archive and disseminate ECG information.

- They are intended to be used by trained operators under the direct supervision of a physician when ECG records are required in the judgement of a physician.

- The arrhythmia detection portion of the CardioSoft / CardioSys stress test system is provided to the user for the convenience of automatic documentation. The CardioSoft / CardioSys offers no diagnostic opinion to the user. Instead, it provides a high fidelity instrument recording ECG waveforms during exercise, for the purpose of providing the operator with a tool to expedite the documentation of a test for which he/she renders his/her own medical opinion.
- They are not designed for intracardial use.
- They are not designed to provide alarms for arrhythmia and ST-segment measurement.
- The devices are not intended for home use.

The intended use of CardioSoft / CardioSys does not differ from the intended use of the predicate device.

Technology

CardioSoft / CardioSys basically employ the same technology as the predicate device.
All parts of the software which determine the medical functionality of the device have been re-used from the predicate device.
The main difference between CardioSoft / CardioSys and the predicate device is that commercially available hardware and system software are used instead of proprietary hardware and software.

Performance

CardioSoft / CardioSys comply with the voluntary standard ANSI/AAMI EC11-1991, ANSI/AAMI ECAR-1987, IEC 601-1, IEC 601-1-1, IEC 601-1-2 and IEC 601-2-25.

CardioSoft and CardioSys passed the EC type-examination and thus bear the CE mark.

The following quality assurance measures were applied to the development of CardioSoft / CardioSys:

Requirements spefication and design reviews, code inspections, software and hardware testing, safety testing, environmental testing, final validation testing by an independent test group, field tests.

The results of these measures demonstrated that CardioSoft / CardioSys are as safe, as effective, and perform as well as the predicate device CARDIOGNOST EK 512.

Signature: Klaus Rudolf Date: March 9, 1995

Name: Klaus Rudolf,
Manager Regulatory Affairs